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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,625	12/18/2001	Ian D. McRury	022956-71 (MIT-239)	3998
21125 7590 06/11/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER EREZO, DARWIN P	
			ART UNIT 3773	PAPER NUMBER
			NOTIFICATION DATE 06/11/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/024,625	MCRURY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Darwin P. Erez	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,20,21 and 23-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,20,21 and 23-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Appeal Brief***

1. In view of the appeal brief filed on 2/11/08, PROSECUTION IS HEREBY REOPENED. A new grounds of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773.

### ***Drawings***

2. New corrected drawings in compliance with 37 CFR 1.84(l) are required in this application because the drawing contains lines, numbers & letters that are not uniformly thick and well defined (poor line quality). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Objections***

3. Claims 23 and 24 are objected to because of the following informalities: The claims are dependent upon a cancelled claim. Appropriate correction is required. When treating the claim on the merits, the claims will be viewed as being dependent upon claim 21.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3, 20, 21, 23-26 and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 3, 20 and 31 each recite a limitation in which the suture contacting element comprises two opposing faces and each face has an electrode disposed thereon. The way the claims are recited, it implies that the device has an additional

"electrode" disposed on the suture contacting element, in addition to the first and second electrode. However, the specification does not show a device having more than two electrodes. Therefore, the claim limitations need to be amended to state that each face of the suture contacting element has one of the first or second electrode disposed thereon, and not an additional electrode.

7. The remaining listed claims are rejected based on their dependence on the rejected claims.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-6, 20-21 and 23-34 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,893,880 to Egan et al.

(claims 1 and 20) Egan discloses a suture welding system capable of fixedly attaching a first length of suture **16** to a second length of suture **18** at a suture welding site, comprising: an electrosurgical energy source (col. 5, ll. 30-33) configured to generate radio frequency waves (col. 8, ll. 13; ultrasonic sound is sound pressure waves whose frequency is above the audible range, which has an upper limit of 20 KHz); first **16** and second lengths **18** of suture; and a suture welding device (Fig. 10A) having a working end comprising a suture contacting element with a first **30** and second electrode **32**, wherein the first electrode **30** receives energy and vibrates and deliver

ultrasonic frequency to the suture and back to the second electrode (col. 8, ll. 12-14); wherein provision of radio frequency energy by the first electrode to the first and second lengths of suture welds the first and second lengths of suture into a fixed attachment (as shown in Fig. 19B).

Egan also discloses a method for welding a first length of suture to a second length of suture to create a fixed attachment therebetween, comprising: (a) providing an electrosurgical energy source (col. 5, ll. 30-33); (b) providing a suture welding device (Fig. 10A) having a working end comprising a suture contacting element with a first **30** and second electrode **32**, wherein the first electrode **30** receives energy and vibrates and deliver ultrasonic frequency to the suture and back to the second electrode (col. 8, ll. 12-14); (c) placing a first length of suture and a second length of suture into contact with the suture contacting element (Fig. 19A); and (d) providing energy from the electrosurgical energy source through the first electrode to the first and second lengths of suture to weld the first length of suture to the second length of suture to create a fixed attachment therebetween (Fig. 19B).

(claims 3-4, 23-24, 27) The suture contacting element has two opposing faces having a variable gap therebetween (col. 8, ll. 14-16), each face having one of the first or second electrode disposed thereon; wherein the suture welding device is configured to be selectively adjustable between an open position and a closed position, wherein the first and second lengths of suture may be placed within the variable gap in the open position and wherein the lengths of suture are constrained within the variable gap in the closed position; wherein the suture contacting element forces the first and second

lengths of suture into close physical contact with each other when the suture welding device is placed in the closed position.

(claims 5-6 and 26) The first and second lengths of suture are made polydioxanone (col. 5, ll. 25-29).

(claim 21) The devices provides radio frequency waves in the ultrasonic range.

(claims 25 and 28-29) The suture contacting element comprises element 32, as shown in Fig. 19B, which is viewed as a pod for preventing the first and second sutures from sliding off of the suture contacting element. As to claim 29, see the rejection to claim 1 and 28.

(claim 30) Egan discloses the use of radio frequency waves in the ultrasonic range; see claim 21.

(claims 31-33) See the rejections to claims 3-4, 23-24, 27 above.

(claim 34) See the rejections to claims 5-6 and 26.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Egan, as applied to the rejection to claim 1 above, and in view of US 6,409,743 to Fenton, Jr.

Egan discloses all the limitations of the claim except for a weldable material that is provided between at least one electrode and at least one length of suture, the weldable material adapted to weld the first length of suture thread to the second length of suture thread upon application of radio frequency energy through the at least one electrode.

However, the use of a weldable material to secure two strands of suture together is well known in the art. For instance, Fenton discloses a collar 1 that is made of a weldable material (col. 6, lines 34-43) and adapted to weld the first length of suture to the second length of suture



Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Egan to include the use of the weldable material because it would help secure the two lengths of strands together prior to placing the strands on the welding device. Furthermore, it has been held that combining prior art elements according to known methods will yield predictable results and would be obvious to one of ordinary skill in the art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

14. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Egan, as applied to the rejection to claim 1 above, and in view of US 5,342,359 to Rydell.

Egan discloses all the limitations of the claim except for the suture welding device including a piston slidably disposed on the suture welding device so as to be translatable in a longitudinal direction to move the first and second lengths of suture into contact with at least one electrode. Instead, Egan merely focuses on the working end of the device instead of the actuator and shaft.

However, the use of an actuator and shaft to effect a working end of a surgical device is well known in the art. It is also well known to use a longitudinally translatable shaft or piston to manipulate a structure in the working end. An example of this arrangement is disclosed by Rydell, wherein a piston 16 is provided to an actuator 36. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an actuator comprising a piston to the device of Egan because it would allow for remote manipulation of the working end, which is known in the art.

***Response to Arguments***

15. Applicant's arguments, see appeal brief, filed 2/11/08, are persuasive.

Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Egan (and in combination with Fenton, Jr. or in combination with Rydell).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Darwin P. Erezol  
Primary Examiner, Art Unit 3773